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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3330-N]

Announcement of the Re-Approval of the American Society of Histocompatibility and Immunogenetics (ASHI) as an Accreditation Organization Under the Clinical Laboratory Improvement Amendments of 1988

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the application of the American Society for Histocompatibility and Immunogenetics (ASHI) for approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for the following specialty and subspecialty areas: General Immunology; Histocompatibility; and ABO/Rh typing. We have determined that the ASHI accreditation meets or exceeds the applicable CLIA requirements. We are announcing the approval and grant ASHI deeming authority for a period of 6 years.

DATES: Effective Date: This notice is effective from **[INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]** TO **[INSERT DATE 6 YEARS AFTER DATE OF PUBLICATION IN FEDERAL REGISTER]**.

FOR FURTHER INFORMATION CONTACT:

Penelope Meyers, (410) 786-3366.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100-578). CLIA amended section 353 of the Public

Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, we may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by us as an accreditation organization under CLIA.

II. Notice of Approval of ASHI as an Accreditation Organization

In this notice, we approve ASHI as an organization that may accredit laboratories for purposes of establishing its compliance with CLIA requirements for the subspecialty of General Immunology, the specialty of Histocompatibility, and the subspecialty of ABO/Rh typing. We have examined the initial ASHI application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that ASHI meets or exceeds the applicable CLIA requirements. We have also determined that ASHI will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of R. Therefore, we grant ASHI approval as an accreditation organization under subpart E of part 493, for the period stated in the "DATES" section of this notice for the subspecialty of General Immunology, the specialty of Histocompatibility, and the subspecialty of ABO/Rh typing. As a result of this determination, any laboratory that is accredited by ASHI during the time period stated in the "DATES" section of this notice will be deemed to meet the CLIA requirements for the listed subspecialties and specialties, and therefore, will generally not be subject to routine inspections by a state survey agency to

determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

III. Evaluation of ASHI Commission Request for Approval as an Accreditation

Organization Under CLIA

The following describes the process used to determine that ASHI accreditation program meets the necessary requirements to be approved by us and that, as such, we may approve ASHI as an accreditation program with deeming authority under the CLIA program. ASHI formally applied to us for approval as an accreditation organization under CLIA for the subspecialty of General Immunology, the specialty of Histocompatibility, and the subspecialty of ABO/Rh typing. In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

A. Subpart E--Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

ASHI submitted its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all its current laboratories and the expiration date of their accreditation, and a detailed comparison of the individual accreditation requirements with the comparable condition-level requirements. The ASHI policies and procedures for oversight of laboratories performing laboratory testing for the subspecialty of General Immunology, the specialty of Histocompatibility, and the subspecialty of ABO/Rh typing are equivalent to those of CLIA in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. ASHI's requirements for monitoring and inspecting laboratories are the same as those previously approved by us for laboratories in the areas of accreditation organization, data management, the inspection process, procedures for removal or withdrawal of accreditation, notification

requirements, and accreditation organization resources. The requirements of the accreditation programs submitted for approval are equal to the requirements of the CLIA regulations.

B. Subpart H--Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

ASHI's requirements are equal to or more stringent than the CLIA requirements at §493.801 through §493.865.

For the specialty of Histocompatibility, ASHI requires participation in at least one external PT program, if available, in histocompatibility testing with an 80 percent score required for successful participation and enhanced PT for laboratories that fail an event. The CLIA regulations do not contain a requirement for external PT for the specialty of Histocompatibility. For the subspecialty of General Immunology, and the subspecialty of ABO/Rh typing, ASHI's requirements are equal to the CLIA requirements.

C. Subpart J--Facility Administration for Nonwaived Testing

ASHI's requirements for the submitted subspecialties and specialties are equal to the CLIA requirements at §493.1100 through §493.1105.

D. Subpart K--Quality System for Nonwaived Testing

The ASHI requirements for the submitted subspecialties and specialties are equal to or more stringent than the CLIA requirements at §493.1200 through §493.1299. For instance, ASHI's control procedure requirements for the test procedures Nucleic Acid Testing and Flow Cytometry are more specific and detailed than the CLIA language for requirements for control procedures. Section 493.1256 paragraphs (c)(1) and (c)(2) require control materials that will detect immediate errors and monitor accuracy and precision of test performance that may be caused by test system failures, environmental conditions and variance in operator performance. ASHI standards provide detailed, specific requirements for the control materials to be used to

meet these CLIA requirements.

E. Subpart M--Personnel for Nonwaived Testing

We have determined that ASHI requirements for the submitted subspecialties and specialties are equal to or more stringent than the CLIA requirements at §493.1403 through §493.1495 for laboratories that perform moderate and high complexity testing. Experience requirements for Director, Technical Supervisor, and General Supervisor exceed CLIA's personnel experience requirements in the specialty of Histocompatibility.

F. Subpart Q--Inspections

We have determined that the ASHI requirements for the submitted subspecialties and specialties are equal to or more stringent than the CLIA requirements at §493.1771 through §493.1780. ASHI inspections are more frequent than CLIA requires. ASHI performs an onsite inspection every 2 years and requires submission of a self-evaluation inspection in the intervening years. If the self-evaluation inspection indicates that an onsite inspection is warranted, ASHI conducts an additional onsite review.

G. Subpart R--Enforcement Procedures

ASHI meets the requirements of subpart R to the extent that it applies to accreditation organizations. ASHI policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, ASHI will deny, suspend, or revoke accreditation in a laboratory accredited by ASHI and report that action to us within 30 days. ASHI also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that ASHI's laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493 subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of laboratories accredited by ASHI may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the State survey agencies, will be our principal means for verifying that the laboratories accredited by ASHI remain in compliance with CLIA requirements. This federal monitoring is an ongoing process.

V. Withdrawal of Approval as an Accrediting Organization

Our regulations at 42 CFR 493.575 provide that we may rescind the approval of an accreditation organization, such as that of ASHI, for cause, before the end of the effective date of approval. If we determine that ASHI has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which ASHI would be allowed to address any identified issues. Should ASHI be unable to address the identified issues within that timeframe, we may, in accordance with the applicable regulations, revoke ASHI's deeming authority under CLIA.

Should circumstances result in our withdrawal of ASHI's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, record keeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The requirements associated with the accreditation process for clinical laboratories under the CLIA program, codified in 42 CFR part

493 subpart E, are currently approved under OMB control number 0938-0686.

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Dated: April 12, 2016.

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

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